

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:     Antoni P. Tomsia

Application No.: 09/845,597

Group No.: 1771

Filed: April 30, 2001

Examiner: Chriss

For: Glass/Ceramic Coatings for Implants

**Commissioner for Patents  
Mail Stop Appeal Brief – Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

**ATTENTION: Board of Patent Appeals and Interferences**

**APPEAL BRIEF (37 C.F.R. section 41.37)**

This brief is in furtherance of the Notice of Appeal, filed in this case on March 5, 2007 and in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed March 26, 2007.

This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. section 41.37(c)):

- I       REAL PARTY IN INTEREST
- II       RELATED APPEALS AND INTERFERENCES
- III       STATUS OF CLAIMS
- IV       STATUS OF AMENDMENTS
- V       SUMMARY OF CLAIMED SUBJECT MATTER
- VI       GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
- VII       ARGUMENT
- VIII       CLAIMS APPENDIX
- IX       EVIDENCE APPENDIX
- X       RELATED PROCEEDINGS APPENDIX

The final page of this brief bears the practitioner's signature.

**I REAL PARTY IN INTEREST (37 C.F.R. section 41.37(c)(1)(i))**

The real party in interest in this appeal is The Regents of the University of California

**II RELATED APPEALS AND INTERFERENCES (37 C.F.R. section 41.37(c)(1)(ii))**

There are no other prior or pending appeals, interferences or judicial proceedings known to the Appellants, the Appellants' legal representative, or the Assignee which may be related to, directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

**II STATUS OF CLAIMS (37 C.F.R. section 41.37(c)(1)(iii))**

1. Claims pending and currently on appeal: 1, 3, 5, 8-12, 20-28, and 30.
2. Claims rejected: 1, 3, 5, 8-12, 20-28 and 30
3. Claims allowed: none
4. Claims canceled: 2, 4, 6-7, 13-19 and 29.

**IV STATUS OF AMENDMENTS (37 C.F.R. section 41.37(c)(1)(iv))**

No amendments have been filed subsequent to final rejection.

## V SUMMARY OF CLAIMED SUBJECT MATTER (37 C.F.R. section 41.37(c)(1)(v))

Independent Claim 1 recites a multilayer article comprising a metal substrate and a first layer comprising a glass composition which comprises, 44.2 to 67.7 wt% SiO<sub>2</sub>, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na<sub>2</sub>O, 2.2 to 6.5 wt% K<sub>2</sub>O and 6.0 wt% P<sub>2</sub>O<sub>5</sub>, wherein the glass composition contains hydroxyapatite particles in an amount of up to 50 wt%. Support for Claim 1 is indicated in the following Table:

Claim 1	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
1. A multilayer article comprising,		
a metal substrate,	Page 8, line 1	Page 2, col 2, 4 <sup>th</sup> full ¶
a first layer comprising an inner and outer surface, said first layer comprising a glass composition,	Page 7, 1 <sup>st</sup> full ¶ Page 8, lines 4-6	Page 2, col 2, 4 <sup>th</sup> full ¶
said glass composition comprising, 44.2 to 67.7 wt% SiO <sub>2</sub> , 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na <sub>2</sub> O, 2.2 to 6.5 wt% K <sub>2</sub> O and 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.	Page 7, 4 <sup>th</sup> full ¶ Page 11, line 5 Page 12, lines 8-9 Fig. 2 and page 5, 5 <sup>th</sup> ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Claim 3 recites the multilayer article of Claim 1 wherein there is a first intermediate layer that has a glass composition as defined in Claim 1 and is located between the substrate and the first layer. Support for Claim 3 is indicated in the following Table:

Claim 3	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
3. The multilayer article of claim 1,		
wherein there is a first intermediate layer having an inner and outer surface, and said first intermediate layer is located between the substrate and first layer,	Page 8, lines 4-6	Page 2, col 2, 4 <sup>th</sup> full ¶
said first intermediate layer comprising a glass composition as defined in claim 1.	Page 7, 1 <sup>st</sup> full ¶ Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2, Table I

Claim 5 recites the multilayer article of Claim 3, which has a second intermediate layer with a glass composition as defined in Claim 1 and located between the first intermediate layer and the substrate. The hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is between

the first layer and the second intermediate layer. Support for Claim 5 is indicated in the following Table:

Claim 5	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
5.The multilayer article of claim 3, wherein there is a second intermediate layer located between the first intermediate layer and the substrate,	Page 8, lines 4-6	Page 2, col 2, 4 <sup>th</sup> full ¶
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,	Page 7, 1 <sup>st</sup> full ¶ Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2, Table I
wherein the hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.	Page 7, 1 <sup>st</sup> full ¶ Page 8, last full ¶ Page 11, lines 6-11 Fig. 2 and page 5, 5 <sup>th</sup> ¶	

Claim 8 recites the multilayer article of Claim 1 with a substrate that is Ti or Ti6Al4V. Support for Claim 8 is indicated in the following Table:

Claim 8	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
8. The multilayer article of claim 1, wherein the substrate is Ti or Ti6Al4V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Claim 9 recites the multilayer article of Claim 3 with a glass composition in the first layer, which comprises about 54.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na<sub>2</sub>O, about 4.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub> and a glass composition in the first intermediate layer, which comprises about 61.1 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na<sub>2</sub>O, about 2.8 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>, and a substrate that is Ti or Ti6Al4V. Support for Claim 9 is indicated in the following Table:

Claim 9	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
9.The multilayer article of claim 3, wherein the glass composition in the first layer comprises about 54.5 wt% SiO <sub>2</sub> , about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na <sub>2</sub> O, about 4.0 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 7, 1 <sup>st</sup> full ¶ Page 8, last full ¶ Page 9, Table 1 Page 11, lines 12-18	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I Page 7, col 2
and the glass composition in the first intermediate layer comprises about 61.1 wt% SiO <sub>2</sub> , about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na <sub>2</sub> O, about 2.8 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 7, 1 <sup>st</sup> full ¶ Page 8, last full ¶ Page 9, Table 1 Page 11, lines 12-18	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I Page 7, col 2
and the substrate is Ti or Ti6Al4V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Claim 11 recites the multilayer article of Claim 3 with a glass composition in the first layer and in the first intermediate layer, which comprises about 56.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na<sub>2</sub>O, about 3.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>. The hydroxyapatite amount in the first layer is 50 wt%, and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V. Support for Claim 11 is indicated in the following Table:

Claim 11	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
11. The multilayer article of claim 3,		
wherein the glass composition in the first layer and the first intermediate layer comprise about 56.5 wt% SiO <sub>2</sub> , about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na <sub>2</sub> O, about 3.0 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub>	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2, Table I
and the hydroxyapatite amount in the first layer is 50 wt%,	Page 7, 4 <sup>th</sup> full ¶ Page 11, line 5	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II
and the substrate is Ti or Ti <sub>6</sub> Al <sub>4</sub> V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Claim 12 recites the multilayer article of Claim 5 with glass compositions in the first layer, the first intermediate layer and the second intermediate layer each comprising about 61.1 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na<sub>2</sub>O, about 2.8 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>. The hydroxyapatite amount in the first layer comprises 50 wt%, and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V. Support for Claim 12 is indicated in the following Table:

Claim 12	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
12. The multilayer article of claim 5,		
wherein the glass composition in the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt% SiO <sub>2</sub> , about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na <sub>2</sub> O, about 2.8 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub>	Page 7, 1 <sup>st</sup> full ¶ Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, col 2, 4 <sup>th</sup> full ¶ Page 2 Table I
and the hydroxyapatite amount in the first layer comprises 50 wt%	Page 7, 4 <sup>th</sup> full ¶ Page 11, line 5	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II
and the substrate is Ti or Ti <sub>6</sub> Al <sub>4</sub> V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶

Independent Claim 20 recites multilayer article comprising a substrate that is Ti or Ti<sub>6</sub>Al<sub>4</sub>V, a first layer and n intermediate layers disposed between the first layer and the substrate. The first layer and the n intermediate layers each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles in an amount up to 50 wt%. The glass composition comprises about 44.2 to about 67.7 wt% SiO<sub>2</sub>,

about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na<sub>2</sub>O, about 2.2 to about 6.5 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>. Support for Claim 20 is indicated in the following Table:

Independent Claim 20	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
20. A multilayer article comprising,		
a metal substrate comprising Ti or Ti <sub>6</sub> Al <sub>4</sub> V,	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 <sup>st</sup> ¶
n intermediate layers, where n is an integer,	Page 8, 1 <sup>st</sup> full ¶ Page 10, line 17	Page 2, col 2, 4 <sup>th</sup> full ¶
a first layer comprising an inner and outer surface,	Page 10, line 18	
said n intermediate layers disposed between the metal substrate and the first layer,	Page 8, 1 <sup>st</sup> full ¶ Page 10, line 19	Page 2, col 2, 4 <sup>th</sup> full ¶
wherein the n intermediate layers and the first layer each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles (HA),	Page 7, 1 <sup>st</sup> full ¶ Page 10, lines 20-22	Page 2, col 2, 4 <sup>th</sup> full ¶
said glass composition comprising, about 44.2 to about 67.7 wt% SiO <sub>2</sub> , about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na <sub>2</sub> O, about 2.2 to about 6.5 wt% K <sub>2</sub> O and about 6.0 wt% P <sub>2</sub> O <sub>5</sub> ,	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I
and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite admixture in an amount of up to 50 wt%.	Page 7, 4 <sup>th</sup> full ¶ Page 11, line 5 Fig. 2 and page 5, 5 <sup>th</sup> ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Claim 21 recites the multilayer article of Claim 20 with a first layer that has a glass composition with a SiO<sub>2</sub> content between about 53 to about 57 wt%. Support for Claim 21 is indicated in the following Table:

Claim 21	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
21. The multilayer article of claim 20, wherein:		
the first layer has a glass composition which has a SiO <sub>2</sub> content between about 53 to about 57 wt%.	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 22 recites the multilayer article of Claim 21, wherein n=2.. Support for Claim 22 is indicated in the following Table:

Claim 22	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
22. The multilayer article of claim 21, wherein n=2.	Page 8, 1 <sup>st</sup> full ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 23 recites the multilayer article of Claim 1, wherein the first layer has a glass composition with a SiO<sub>2</sub> content between about 53 to about 57 wt%.. Support for Claim 23 is indicated in the following Table:

Claim 23	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
23.The multilayer article of claim 1, wherein:		
the first layer has a glass composition which has a SiO <sub>2</sub> content between about 53 to about 57 wt%.	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 24 recites the multilayer article of Claim 23 wherein n=2. Support for Claim 24 is indicated in the following Table:

Claim 24	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
24.The multilayer article of claim 23, wherein n=2.	Page 8, 1 <sup>st</sup> full ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 25 recites the multilayer article of Claim 20 wherein the first layer has a glass composition with a SiO<sub>2</sub> content between about 56 to about 67.7 wt%. Support for Claim 25 is indicated in the following Table:

Claim 24	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
25.The multilayer article of claim 20, wherein:		
the first layer has a glass composition which has a SiO <sub>2</sub> content between about 56 to about 67.7 wt%.	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 26 recites the multilayer article of Claim 25 wherein n=2. Support for Claim 26 is indicated in the following Table:

Claim 26	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
26.The multilayer article of claim 25, wherein n=2.	Page 8, 1 <sup>st</sup> full ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 27 recites the multilayer article of Claim 1 wherein the first layer has a glass composition with a SiO<sub>2</sub> content between about 56 to about 67.7 wt%. Support for Claim 27 is indicated in the following Table:

Claim 27	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
27. The multilayer article of claim 1, wherein:		
the first layer has a glass composition which has a SiO <sub>2</sub> content between about 56 to about 67.7 wt%.	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I

Claim 28 recites the multilayer article of Claim 27 wherein n=2. Support for Claim 28 is indicated in the following Table:

Claim 28	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
28.The multilayer article of claim 27, wherein n=2.	Page 8, 1 <sup>st</sup> full ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2

Claim 30 recites the multilayer article of Claim 3 wherein there is a second intermediate layer located between the first intermediate layer and the substrate. The first layer, first intermediate layer and second intermediate layer all comprising a glass composition as defined in Claim 1, and the SiO<sub>2</sub> concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer. Support for Claim 30 is indicated in the following Table:

Claim 30	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
30.The multilayer article of claim 3,		
wherein there is a second intermediate layer located between the first intermediate layer and the substrate,	Page 8, 1 <sup>st</sup> full ¶	Page 2, col 2, 4 <sup>th</sup> full ¶ Page 7, col 1 last ¶ – col 2
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,	Page 9, Table 1	Page 2, col 2, 1 <sup>st</sup> full ¶ Page 2, Table I
wherein the SiO <sub>2</sub> concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.	Page 11, lines 12-18	Page 7, col 1 last ¶ – col 2



**VI      GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R. section 41.37(c)(1)(vi))**

1) Anticipation by “HA-bioactive glass composites...”

Claims 1, 8 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by the article titled “HA-bioactive glass composites: High temperature reactivity and ‘in-vitro’ behavior” by Pazo, et al., published 1996.

2) Anticipation by “Glass-hydroxyapatite coatings...”

Claims 1, 3, 5, 8-12 and 20-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000.

3) Unpatentable over “Glass-hydroxyapatite coatings...” and further in view of “A multilayer approach to fabricate bioactive glass...”

Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000, and further in view of “A multilayer approach to fabricate bioactive glass coatings on Ti alloys,” by Gomez-Vega et al, published June 1999.

## VII ARGUMENT (37 C.F.R. 41.37(c)(1)(vii))

### 1) Anticipation by “HA-bioactive glass composites...”

Claims 1, 8 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by the article titled “HA-bioactive glass composites: High temperature reactivity and ‘in-vitro’ behavior” by Pazo, et al., herein referred to as “Pazo”.

Independent Claim 1 recites a multilayer article comprising, a metal substrate and a first layer comprising a glass composition which comprises, 44.2 to 67.7 wt% SiO<sub>2</sub>, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na<sub>2</sub>O, 2.2 to 6.5 wt% K<sub>2</sub>O and 6.0 wt% P<sub>2</sub>O<sub>5</sub>, wherein the glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.

The Examiner asserts that, “Regarding Claim 1, the reference teaches a multilayered article (see text of page 1733 and Figures 6 and 7) comprising a Ti or Ti alloy substrate (see line 6 of abstract) and a first layer comprising a glass of the claimed composition (see page 1729, first paragraph under "Materials and Methods), further comprising HA in an amount of 25% (up to 50%) (page 1729, last paragraph).”

The Pazo abstract (including line 6) said, “...In a previous investigation a new MgO-containing BAG has been developed. This glass combines both high bioactivity and excellent adhesion to Ti and Ti alloys.” The abstract said that the glass *has excellent adhesion* to Ti and Ti alloys. The abstract did not describe a multilayered structure with a metal substrate and a first layer comprising a glass composition, as recited in Claim 1.

The text of page 1733 and Figures 6 and 7 in Pazo referred to the results of two experiments. Figure 6 and the text referred to a composite with a 20% BAG and 80% HA composition obtained by hot pressing at 850°C after soaking in SBF (simulated biological fluid) for 30 days. The result, as shown in Figure 6 and described in the text, was a continuous apatite layer on the surface of the composite. Figure 7 referred to an A-3 glass/coarse HA sample fired at 850°C for 10 minutes after 48 days soaking in SBF. Preparation of this sample was further described in paragraph 3 on page 1730 thus, “...A-3 glass plates ... were coated with HA coarse ... grains and fired at 850°C for 1 h.” The result, described in Figure 7, was a new amorphous HA coating on the A-3 glass and on the coarse HA grain surfaces. Pazo included a metal substrate, as recited in Claim 1, in none of his samples either before or after soaking in SBF.

Appellants respectfully traverse the rejection and submit that Pazo failed to teach each and every feature of independent Claim 1.

Dependent Claims 8 and 23 each depend from independent Claim 1 and therefore include all the features and limitations thereof. Furthermore, the dependent claims add additional distinguishing features of particular utility. Accordingly, Appellants submit that dependent Claims 8 and 23 are also allowable over Pazo.

2) Anticipation by “Glass-hydroxyapatite coatings...”

Claims 1, 3, 5, 8-12 and 20-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000.

The pending application claims priority to U.S. Provisional Application 60/201,556, filed May 1, 2000. As this rejection is based on a reference that cannot be considered prior art under 102(b), Appellants assert that the rejection is moot and should be withdrawn.

3) Unpatentable over “Glass-hydroxyapatite coatings...” and further in view of “A multilayer approach to fabricate bioactive glass...”

Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000, and further in view of “A multilayer approach to fabricate bioactive glass coatings on Ti alloys,” by Gomez-Vega et al, published June 1999.

The pending application claims priority to U.S. Provisional Application 60/201,556, filed **May 1, 2000**. As this rejection is based on a reference that cannot be considered prior art under 102(b), Appellants assert that the rejection is moot and should be withdrawn.

## VIII CLAIMS APPENDIX (37 C.F.R. section 41.37(c)(1)(viii))

1. A multilayer article comprising,  
a metal substrate,  
a first layer comprising an inner and outer surface,  
said first layer comprising a glass composition,  
said glass composition comprising,  
44.2 to 67.7 wt% SiO<sub>2</sub>, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na<sub>2</sub>O, 2.2 to 6.5 wt% K<sub>2</sub>O and 6.0 wt% P<sub>2</sub>O<sub>5</sub>,  
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.
3. The multilayer article of claim 1,  
wherein there is a first intermediate layer having an inner and outer surface,  
and said first intermediate layer is located between the substrate and first layer,  
said first intermediate layer comprising a glass composition as defined in claim 1.
5. The multilayer article of claim 3,  
wherein there is a second intermediate layer located between the first intermediate layer and the substrate,  
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,  
wherein the hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.
8. The multilayer article of claim 1,  
wherein the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V.

9. The multilayer article of claim 3,  
wherein the glass composition in the first layer comprises about 54.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na<sub>2</sub>O, about 4.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>,  
and the glass composition in the first intermediate layer comprises about 61.1 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na<sub>2</sub>O, about 2.8 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>,  
and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V.
10. The multilayer article of claim 3,  
wherein the glass composition in the first layer comprises about 52.7 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.1 wt% MgO, about 17.0 wt% Na<sub>2</sub>O, about 4.6 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>,  
and the glass composition in the first intermediate layer comprises:  
about 56.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na<sub>2</sub>O, about 3.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub>,  
and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V.
11. The multilayer article of claim 3,  
wherein the glass composition in the first layer and the first intermediate layer comprise about 56.5 wt% SiO<sub>2</sub>, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na<sub>2</sub>O, about 3.0 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub> and the hydroxyapatite amount in the first layer is 50 wt%,  
and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V.
12. The multilayer article of claim 5,  
wherein the glass composition in the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt% SiO<sub>2</sub>, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na<sub>2</sub>O, about 2.8 wt% K<sub>2</sub>O and about 6.0 wt% P<sub>2</sub>O<sub>5</sub> and the hydroxyapatite amount in the first layer comprises 50 wt%  
and the substrate is Ti or Ti<sub>6</sub>Al<sub>4</sub>V.

20. A multilayer article comprising,  
a metal substrate comprising Ti or  $\text{Ti}_6\text{Al}_4\text{V}$ ,  
n intermediate layers, where n is an integer,  
a first layer comprising an inner and outer surface,  
said n intermediate layers disposed between the metal substrate and the first layer,  
wherein the n intermediate layers and the first layer each independently comprise a  
glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite  
particles (HA),  
said glass composition comprising,  
about 44.2 to about 67.7 wt%  $\text{SiO}_2$ , about 10.1 to about 23.4 wt% CaO, about 5.7 to  
about 13.3 wt% MgO, about 10.3 to about 23.6 wt%  $\text{Na}_2\text{O}$ , about 2.2 to about 6.5 wt%  
 $\text{K}_2\text{O}$  and about 6.0 wt%  $\text{P}_2\text{O}_5$ ,  
and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite  
admixture in an amount of up to 50 wt%.
21. The multilayer article of claim 20, wherein:  
the first layer has a glass composition which has a  $\text{SiO}_2$  content between about 53 to  
about 57 wt%.
22. The multilayer article of claim 21, wherein:  
n=2.
23. The multilayer article of claim 1, wherein:  
the first layer has a glass composition which has a  $\text{SiO}_2$  content between about 53 to  
about 57 wt%.
24. The multilayer article of claim 23, wherein:  
n=2.
25. The multilayer article of claim 20, wherein:  
the first layer has a glass composition which has a  $\text{SiO}_2$  content between about 56 to  
about 67.7 wt%.

26. The multilayer article of claim 25, wherein:

n=2.

27. The multilayer article of claim 1, wherein:

the first layer has a glass composition which has a SiO<sub>2</sub> content between about 56 to about 67.7 wt%.

28. The multilayer article of claim 27, wherein:

n=2.

30. The multilayer article of claim 3,

wherein there is a second intermediate layer located between the first intermediate layer and the substrate,

said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,

wherein the SiO<sub>2</sub> concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.

## **IX EVIDENCE APPENDIX (37 C.F.R. section 41.37(c)(1)(ix))**

A letter from Greg Geiger, American Ceramic Society Development Editor for books states that the publication of the proceedings of the Bioceramics: Materials and Applications symposium, held at the 101<sup>st</sup> Annual meeting of The American Ceramic Society occurred in February 2000. The reference “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, relied upon by the Examiner as prior art, was part of this publication. This evidence was submitted to the Examiner on May 2, 2003 and is submitted here on the following page in support of the present appeal brief.





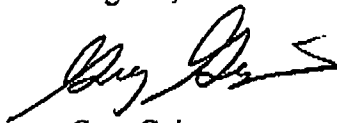
May 2, 2003

To Whom It May Concern:

This letter is in regard to The American Ceramic Society publication: Bioceramics: Materials and Applications III, Ceramic Transactions, Volume 110, edited by Laurie George, Richard P. Rusin, Gary S. Fischman, and Vic Janas; copyright 2000; ISBN 1-57498-102-1.

This book was based on the proceedings of the Bioceramics: Materials and Applications symposium, held at the 101<sup>st</sup> Annual Meeting of The American Ceramic Society in Indianapolis, Indiana, April 25-28, 1999. The book was printed in February of 2000 with the first books being mailed to customers on 2/23/2000.

Regards,



Greg Geiger  
Development Editor, Books  
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**X      RELATED PROCEEDINGS APPENDIX (37 C.F.R. section 41.37(c)(1)(x))**

There are no known related proceedings.

Respectfully Submitted:

Date: April 26, 2007

/R'Sue Popowich Caron/

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